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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,962	05/31/2006	Erik Buntinx	29248/29	8917

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EXAMINER	
PIHONAK, SARAH	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
12/20/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,962	BUNTINX, ERIK	
	Examiner	Art Unit	
	SARAH PIHONAK	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *110-142* is/are pending in the application.

5a) Of the above claim(s) *141 and 142* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *110-140* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/BE04/00172, filed on 12/2/04.

Priority

This application is a 371 (national stage application) of PCT/BE04/00172, filed on 12/4/04. The filing date of the instant application is 5/31/06. This application claims priority to the following foreign applications: 2451798, filed on 12/2/03; 03447279.5, filed on 12/2/03; 04447001.1, filed on 1/5/04; 04447066.4, filed on 3/18/04; 2461248, filed on 3/18/04; 04025035.9, filed on 10/21/04; 2004-349085, filed on 11/4/04; and 2487529, filed on 11/15/04. Certified copies of the foreign priority applications have been received. The instant application is also a continuation in part of the following applications: 10725965, filed on 12/2/03; 10/752423, filed on 1/6/04; and 10803793, filed on 3/18/04. Application No. 10/725965, 10/752423, and 10803793 provide support to the instant claims. Therefore, the priority and effective filing date given to the instant claims is that of the earliest filed application, 12/2/03.

Response to Remarks

1. Claims 110-142 are pending as of the reply filed on 10/28/2011; claims 141-142 were previously withdrawn from consideration, due to the restriction requirement.

Applicants' arguments, with regards to the rejection under 35 USC 103(a) as being unpatentable over Cremers et. al., in view of Van Oekelen et. al., and further in

view of Sanchez et. al., have been fully considered and are found persuasive. The rejection under 35 USC 103(a) is withdrawn.

A rejection for obviousness type double patenting has been made in further consideration of claims 110-140, which will be discussed in the office action. Accordingly, this action is made NON-FINAL.

Applicants' arguments and claim amendments with regards to the rejection of claims 134-137 under 35 USC 112, second paragraph for lacking antecedent basis for pharmaceutically acceptable salts have been fully considered but are not found persuasive. The Applicants have amended claims 134-137 to recite the pharmaceutically acceptable salts of pipamperone and escitalopram, respectively; however, these claims are dependent upon claims 110 and 113 respectively, and claims 110 and 113 do not cite pharmaceutically acceptable salts. The rejection under 35 USC 112, second paragraph is maintained for reasons of record, and will be reiterated in the office action. The examiner suggests amending claims 110 and 113 to include pharmaceutically acceptable salts of pipamperone or escitalopram, to overcome this rejection.

2. Claims 110-140 were examined.

3. Claims 110-140 are rejected.

Claim Rejections-Obviousness Type Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 110-140 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-98 of U.S. Patent No. 7,884,096 in view of Sanchez et. al., US Patent Publ. 2002/0086899. The claims of the instant application are directed to a pharmaceutical composition comprised of escitalopram in a dose of 10-20 mg., and pipamperone in a dose of 5-15 mg., while the claims of the US Patent are directed to a pharmaceutical composition comprised of citalopram in a dose from 10-40 mg., and pipamperone in a dose of 5-15 mg. While the claims are not identical, they are not patentably distinct from each other because escitalopram is the (S)-enantiomer of citalopram, as evidenced by Sanchez et al. (Abstract). Sanchez et. al. discloses that both citalopram and escitalopram are used to treat panic disorders and depression (Sanchez, Abstract; p. 1, paragraphs [0002-0004]). Escitalopram and citalopram are both taught to have similar utility; therefore, it would have been prima facie obvious to have substituted one compound for the other, as both escitalopram and citalopram are useful for treating panic and depression. Both sets of claims are as such not distinct from each other.

Claim Rejections-35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 134-137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claims 134-137 recite the limitation of a pharmaceutically acceptable salt of pipamperone or escitalopram. However, these claims are dependent upon claims 110 and 113, which do not cite pharmaceutically acceptable salts. There is insufficient antecedent basis for this limitation in the claims.

Conclusion

8. Claims 110-140 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627